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Kuniyoshi Nakashima

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COOPER & DUNHAM, LLP  
30 Rockefeller Plaza  
20th Floor  
NEW YORK, NY 10112

EXAMINER

BROOKS, JULIAN D

ART UNIT

PAPER NUMBER

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/552,136	<b>Applicant(s)</b> NAKASHIMA ET AL.	
	<b>Examiner</b> JULIAN D. BROOKS	<b>Art Unit</b> 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 29 November 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,4,6-11,14 and 16-26 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,4,6-11,14 and 16-26 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Amendment***

1. Claims 1-20 were pending in this application [10/06/2005].
2. Claims 1, 4, and 11 were amended [10/23/2008].
3. Claim 21-23 were added [10/23/2008].
4. Claims 1, 11 and 23 were amended [04/13/2009].
5. Claims 1 and 11 were amended [08/31/2009].
6. Claims 24 and 25 were added [08/31/2009]
7. Claims 1-25 were pending [08/31/2009].
8. Claims 1, 4, 11, and 14 were amended [03/29/2010].
9. Claims 2, 3, 12, and 13 were cancelled [03/29/2010].
10. Claims 1, 4-11, and 14-25 were pending [03/29/2010].
11. Claims 5 and 15 have been cancelled [11/29/2010].
12. Claims 1 and 11 have been amended [11/29/2010].
13. Claims 26 has been newly added [11/29/2010].
14. Claims 1, 4, 6-11, 14, and 16-26 are pending [11/29/2010].

### ***Claim Rejections - 35 USC § 103***

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**16. Claims 1, 4, 6, 9-11, 14-16, 19, 20, 24 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabol et al., U.S. Patent Publication No. 2004/0101086 A1, filed on 10/27/2002, [herein Sabol], in view of Kim et al., U.S. Patent No. 6278761, published on 08/21/2001, [herein Kim], in view of Wiemker et al., PCT WO 02/103065, published 12/27/2002, [herein Wiemker] and further in view of Kvist et al., "Total and visceral adipose-tissue volumes derived from measurements with computed tomography in adult men and women: predictive equations.", published on 1988, [herein Kvist].**

With respect to claim 1, Sabol discloses "A medical image diagnosing support apparatus" (See Figures 1 & 2)

"comprising: a first extraction means which extracts a body region of a subject from a tomographic image of the subject acquired by a medical tomographic apparatus" (Page 4, Paragraphs 0040, 0043, & 0044, Page 5, Paragraph 0046, and see Figure 5, extraction means corresponds to Sabol's computer for tissue characterization);

"a third extraction means which extracts a total body adipose region from the body region" (Page 5, Paragraph 0046, lines 7-11, total body adipose region corresponds to Sabol's fatty tissue);

"a display control means which controls display of the tomographic image on an image display device" (Page 3, Paragraph 0031, and Page 5, Paragraph 0046, lines 11-23).

It is however noted that Sabol fails to explicitly disclose “and removes an epidermal tissue layer region from the body region”,

“a second extraction means which automatically (a) searches the tomographic image for a predetermined range of CT values corresponding to an abdominal wall muscle layer to determine from a histogram of the CT values in the predetermined range a most frequently occurring CT value in the predetermined range, (b) sets a threshold by utilizing the most frequently occurring CT value in the predetermined range, (c) extracting, while utilizing the threshold, an abdominal wall muscle layer region as a non-adipose region from the body region from which the epidermal tissue region has been removed, and (d) sets a line surrounding the abdominal wall muscle layer region based on positional information of the abdominal wall muscle layer region extracted in (c)”;

“a separation means which separates the total body adipose region into a visceral adipose region and a subcutaneous adipose region based on whether a specified region is located inside or outside of the line surrounding the abdominal wall muscle layer region” and

“[display] with clear indication of the visceral adipose region and the subcutaneous adipose region”, as claimed.

On the other hand Kim teaches “a second extraction means which automatically (a) searches the tomographic image for a predetermined range of CT values corresponding to an abdominal wall muscle layer to determine from a histogram of the CT values in the predetermined range a most frequently occurring CT value in the

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predetermined range, (b) sets a threshold by utilizing the most frequently occurring CT value in the predetermined range” (Kim: Col. 3, lines 10-14, & 38-67, and Col. 4, lines 1-17, Kim describes using histogram peaks, which correspond to most frequently occurring CT value, to determine a threshold range, moreover, this range is limited to an area in which non-fat tissue will not be detected, specifically See Wiemker as cited below which supports that Kim's Hounsfield ranges includes abdominal wall muscle),

“a separation means which separates the total body adipose region into a visceral adipose region and a subcutaneous adipose region” (Col. 3, lines 15-31, visceral and subcutaneous adipose regions correspond to Kim's intra-abdominal cavity fat and subcutaneous fat respectively),

“[display] with clear indication of the visceral adipose region and the subcutaneous adipose region” (Col. 3, lines 18-38, clear indication corresponds to Kim's high contrast image).

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to incorporate the teachings of Kim into the apparatus for quantifying tissue fat content of Sabol because both Kim and Sabol are directed to medical imaging specifically for viewing body tissue (Sabol: abstract; and Kim: Col. 2, lines 10-23), more particularly both are directed segmenting and distinguishing between the types of imaged body tissue (Sabol: Page 1, Paragraph 0008, also see Figures 5 & 6; and Kim: Abstract) and both are in the same field of endeavor. Furthermore, incorporating the setting of threshold ranges based on pixel frequency in a range provided by the non adipose region of Kim into Sabol would have allowed users of

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Sabol's multi-energy computed tomography system to not only produce an image distinguishing lean and fat tissue (Sabol: Page 1, Paragraph 0007-0008), but also particularly further segment the imaged fat tissue into subcutaneous and intra-abdominal areas as suggested by Kim (Kim: abstract). Therefore, combination of Sabol and Kim, prior art would have been obvious to one of ordinary skill in the art at the time of invention because to apply the segmentation of subcutaneous and intra-abdominal fat tissue of as taught by Kim, to improve the quantifying fat tissue content CT system as disclosed by Sabol would have yielded the predictable result of improving diagnostic ability by determining and analyzing a subcutaneous to intra-abdominal fat ratio as suggested by Kim (Kim: Page 1, lines 38-46).

It is still however noted that Sabol as modified by Kim fails to explicitly teach "removes an epidermal tissue layer region from the body region",

"(c) extracting, while utilizing the threshold, an abdominal wall muscle layer region as a non-adipose region from the body region from which the epidermal tissue region has been removed, and (d) sets a line surrounding the abdominal wall muscle layer region based on positional information of the abdominal wall muscle layer region extracted in (c)"

"[separating] based on whether a specified region is located inside or outside of the line surrounding the abdominal wall muscle layer region", as claimed.

On the other hand Sabol as modified by Kim and Wiemker teaches "and removes an epidermal tissue layer region from the body region" (See figure 2, and Page 8, lines

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24-28, Wiemker teaches setting thresholds to visualize particular tissue types which includes skin to muscle transition),

“(c) extracting, while utilizing the threshold, an abdominal wall muscle layer region as a non-adipose region from the body region from which the epidermal tissue region has been removed,” (Wiemker: Page 8, lines 15-28, and See Figure 2, Wiemker teaches a specific Hounsfield value for extracting/visualizing an abdominal wall muscle layer from the same body region which skin has been removed).

It would have been obvious to one of ordinary skill in the art to incorporate Wiemker into Sabol as modified by Kim because Sabol as modified by Kim contains a base process of extracting body tissue regions using histogram based thresholds in defined Hounsfield CT value ranges, which the claimed invention can be seen as an “improvement” in that the threshold can be set to explicitly extract an abdominal wall muscle region. Wiemker contains a known technique of setting a Hounsfield for identifying an abdominal wall muscle region which is applicable to the base processes since the base process already deals in this Hounsfield range. Therefore, Wiemker’s known technique of identifying abdominal muscle would have been recognized by one of ordinary skill in the art as applicable to the base process of Sabol as modified by Kim and the results would have been predictable and resulted in selecting a histogram peak corresponding muscle and there thus being able to visualize the abdominal muscle which results in an improved process by increasing the visualizing and distinguishing capabilities.



It is still however noted that Sabol as modified by Kim and Wiemker fail to teach “(d) sets a line surrounding the abdominal wall muscle layer region based on positional information of the abdominal wall muscle layer region extracted in (c)” and “[separating] based on whether a specified region is located inside or outside of the line surrounding the abdominal wall muscle layer region”.

On the other hand Sabol as modified by Kim, Wiemker, and further by Kvist teaches “(d) sets a line surrounding the abdominal wall muscle layer region based on positional information of the abdominal wall muscle layer region extracted in (c)” (Kvist: Page 1352, Col. 2, final 2 paragraphs; and Sabol: Page 5, Paragraph 0047, lines 5-20, Kvist’s teaches encircling an abdominal muscle region, furthermore, Sabol teaches delineating a region of interest and explicitly states that this is accomplished automatically, it would be reasonable for one of ordinary skill in the art to automatically delineate the abdominal wall region as described in Kvist, furthermore, the delineation is inherently based on positional information of the region, since the encircling of a particular region from a plurality of regions requires some form of “knowing” or being able to identify where that region is located; Kvist and Sabol teach encircling “halfway through” and/or delineating based on “shape and size” which are all indicative of position) and

“[separating] based on whether a specified region is located inside or outside of the line surrounding the abdominal wall muscle layer region” (Kvist: Abstract: lines 8-10, Page 1352, Col. 2, final 2 paragraphs, and Page 1353, Col. 1, and Figure 1).

It would have been obvious to one of ordinary skill in the art to incorporate Kvist into Sabol as modified by Kim and Wiemker because Kvist, Kim, Wiemker and Sabol are all directed to medical imaging specifically for viewing body tissue (Sabol: abstract; Kim: Col. 2, lines 10-23; and Kvist: Abstract, lines 1-2; Wiemker: abstract), more particularly all are then directed to segmenting and distinguishing between the types of imaged body tissue (Sabol: Page 1, Paragraph 0008, also see Figures 5 & 6; Kim: Abstract; and Kvist: Page 1352, Col. 2, final 2 paragraphs, and Figure 1; Wiemker: Figure 2) and all are in the same field of endeavor. Furthermore, Sabol as modified by Kim and Wiemker contain a base process visualizing lean and fat abdominal tissue, specifically, abdominal wall muscle, visceral and subcutaneous fat, by appropriately defining a Hounsfield range and setting appropriate thresholds which the claimed invention can be seen as an "improvement" in that a line set on the abdominal wall muscle is used to determine visceral and subcutaneous fat by determining if fat is inside or outside of the line, i.e. inside or outside of the abdominal wall muscle. Kvist contains a known technique for delineating a line on the abdominal wall muscle in order to measure fat area inside the line and outside the line that is applicable to the base device. Furthermore, Sabol teaches a known technique of automatic delineation for a region of interest. Kvist's known technique of fat determining with respect to the muscle wall would have been recognized by one of ordinary skill in the art as applicable to the base process of Sabol as modified by Kim and Wiemker and the results would have been predictable and resulted in Sabol's delineation automatically delineating an identified abdominal wall muscle, identified through appropriate threshold setting, and

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calculating areas inside and outside the delineation to determine visceral and subcutaneous fat which results in an improved process by improving diagnostic ability by determining particular areas, performing volumetric calculations, and anthropometric measurements for improved analyzation of the abdominal region.

With respect to claim 4, Sabol as modified by Kim, Wiemker, and Kvist teaches “wherein the second extraction means performs peripheral edge recognition processing of the non-adipose region” (Page 4 & 5 Paragraph 0045, lines 7-11), “sets a plurality of attention points on a recognized peripheral edge” (Page 5, Paragraph 0047, lines 5-19, setting a plurality of points corresponds to Sabol’s delineating the region),

“wherein the separation means separates the total body adipose region into a visceral adipose region and a subcutaneous adipose region based on the outline of the non-adipose region extracted” (Sabol: Page 5, paragraphs 0046, and 0047, Sabol delineates and extracts an organ which is not fat, furthermore see Figures 5 and 8, regions of various tissue is outlined. Furthermore see Page 4 & 5, paragraph 0045, Sabol clearly suggest using segmentation techniques such as edge detection).

It is however noted that Sabol as modified by Kim and Kvist fails to explicitly disclose “and interpolates spaces between the plurality of attention points by higher order spline interpolation to extract an outline of the non-adipose region”, and, as claimed.

On the other hand Sabol states on Page 5, Paragraph 0047, lines 5-19 that a region of interest is delineated manually or automatically, moreover utilizing a higher

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order spline interpolation for outlining an imaged object is well known in that art as admitted applicant on Page 3, lines 28-29 of "Amendments to the specification". It would be obvious to one of ordinary skill in the art to implement a well known in the art higher order spline interpolation technique because it would provide a sufficient delineation technique while also achieving a small interpolation error.

With respect to claim 6, Sabol as modified by Kim, Wiemker, and Kvist discloses "wherein the third extraction means extracts the total body adipose region by subtracting the non-adipose region from the body region" (Sabol: Col. 3, lines 35-38).

With respect to claim 9, Sabol as modified by Kim, Wiemker, and Kvist teaches "further comprising an area ratio calculation means which calculates area ratios of the total body adipose region" (Sabol: Page 5, Paragraph 0048, ratio corresponds to Kim's fat/lean ratio),

"the visceral adipose region, and the subcutaneous adipose region" (Kim: Col. 1, lines 38-46, and See Figure 8),

"wherein the display control means controls to display the area ratios calculated by the area ratio calculation means on the image display device" (Sabol: Page 5, Paragraph 0049).

With respect to claim 10, Sabol as modified by Kim, Wiemker, and Kvist teaches "further comprising a print output means which prints and outputs the tomographic

image and the area ratios controlled to be displayed on the image display device by the display control means” (Kim: Figures 2-7, tomographic images are outputted and printed as demonstrated by Kim’s figures).

With respect to claim 11, claim 11 is the method embodiment of the above claim 1 and therefore rejected on the same basis as the above rejected claim 1. Further Sabol discloses “A medical image diagnosing support method” (See Figures 6 and 7).

With respect to claim 14, claim 14 is rejected on the same basis as the above rejected claim 4.

With respect to claim 16, claim 16 is rejected on the same basis as the above rejected claim 6.

With respect to claim 19, claim 19 is rejected on the same basis as the above rejected claim 9.

With respect to claim 20, claim 20 is rejected on the same basis as the above rejected claim 10.

With respect to claim 24, Sabol as modified by Kim, Wiemker, and Kvist “wherein the second extraction means sets the line surrounding the non-adipose region using

peripheral edge recognition processing” (Page 5, Paragraph 0047, peripheral edge recognition processing corresponds to Sabol's algorithm for delineating using shape and size information, since delineate means to mark the outline).

With respect to claim 25, claim 25 is rejected on the same basis as the above rejected claim 24.

**Claims 7, 8, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabol et al., U.S. Patent Publication No. 2004/ 0101086 A1, filed on 10/27/2002, Kim et al., U.S. Patent No. 6278761, published on 08/21/2001, Wiemker et al., PCT WO 02/103065, published 12/27/2002, [herein Wiemker], and Kvist et al., “Total and visceral adipose-tissue volumes derived from measurements with computed tomography in adult men and women: predictive equations.”, published on 1988, [herein Kvist], as applied to claims 1 and 11 above and further in view of Wollenweber, US Patent No. 7155047 B2, filed on 12/20/2002.**

With respect to claim 7, Sabol as modified by Kim, Wiemker, and Kvist teaches “body adipose measurement” (Sabol: abstract)

It is noted that Sabol, Kim, Wiemker, and Kvist fail to teach “further comprising a determination means which determines whether the tomographic image is suitable for”, and

“wherein the display control means controls to display a determination result by the determination means on the image display device”, as claimed.

On the other hand Wollenweber teaches “further comprising a determination means which determines whether the tomographic image is suitable for” (Col. 7, lines 5-34, & 54-62, and Figure 2, item 68, determination of suitable image corresponds to Wollenweber's thresholding to determine images with quality problems);

“wherein the display control means controls to display a determination result by the determination means on the image display device” (Col. 7, lines 47-53 determination result corresponds to Wollenweber's peaks exceeding thresholds).

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to incorporate the teachings of Wollenweber into the modified system for quantifying tissue fat content of Sabol as modified by Kim, Wiemker, and Kvist because all, Wollenweber, Kim, Sabol, Wiemker, and Kvist are directed to medical imaging (Wollenweber: Col. 1, lines 40-55, and Figures 1 & 2; Sabol: abstract; Kim: Col. 2, lines 10-23; and Kvist: Abstract, lines 1-2; Wiemker: abstract), more particularly both Wollenweber and Sabol are directed to computed tomography imaging systems with similar basic techniques (Sabol: Page 2 -3, Paragraph 0029; and Wollenweber: Col. 5, lines 17-39). Furthermore, incorporate the teachings of Wollenweber into Sabol as modified by Kim, Wiemker and Kvist would have allowed users of Sabol's multi-energy computed tomography system to not only produce an image distinguishing lean, subcutaneous, and intra-abdominal fat tissue (Sabol: Page 1, Paragraph 0007-0008; and Kim: abstract), but also assesses the loss of image quality

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due to lower system sensitivity as clearly suggested by Wollenweber (Wollenweber: Col. 1, lines 6-20). Therefore, it would have been obvious to one of ordinary skill in the art to use the multiple dataset collection and analyzation of Wollenweber to analyze and threshold the obtained images in Sabol's CT system to determine quality images because Wollenweber further suggest that image quality is inversely proportional to patient size (Wollenweber: Col. 1, lines 21-30), while Sabol's system is directed towards examining images of patients of larger size (Sabol: Page 1, Paragraph 0005 and 0006).

With respect to claim 8, Sabol, as modified by Kim, Wiemker, Kvist, and Wollenweber teach "wherein when the determination means obtains error information that the tomographic image is not obtained from a site suitable for body adipose measurement of the subject or not acquired by a predetermined medical tomographic apparatus, the display control means controls to display the error information on the image display device" (Wollenweber: Col. 7, lines 41-53 error information corresponds to Wollenweber's peaks exceeding thresholds, and Wollenweber's white ban artifacts displayed in erroneous images).

With respect to claim 17, claim 17 is rejected on the same basis as the above rejected claim 7.

With respect to claim 18, claim 18 is rejected on the same basis as the above rejected claim 8.



**17. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sabol et al., U.S. Patent Publication No. 2004/ 0101086 A1, filed on 10/27/2002, Kim et al., U.S. Patent No. 6278761, published on 08/21/2001, Wiemker et al., PCT WO 02/103065, published 12/27/2002, [herein Wiemker], and Kvist et al., “Total and visceral adipose-tissue volumes derived from measurements with computed tomography in adult men and women: predictive equations.”, published on 1988, [herein Kvist], as applied to claim 1 above and further in view of Rosania et al. U.S. Patent Application Publication No. 2003/0059093 A1, published on 03/27/2003, [herein Rosania].**

With respect to claim 21, Sabol as modified by Kim, Wiemker, and Kvist discloses “wherein the separation means extracts a region between a contracted circumscribed circle and a muscle region as the subcutaneous adipose region” (Kvist: Page 1353, See Figure 1),

It is however noted that Sabol as modified by Kim and Kvist fails to explicitly “when the circumscribed circle, which circumscribes the body region divided radially into predetermined numbers having the barycenter of the body region as the center, is contracted until the circle circumscribes the muscle region which is extracted by performing threshold processing to the body region” as claimed.

On the other hand Sabol as modified by Kim, Wiemker, Kvist and Rosania suggest “when the circumscribed circle, which circumscribes the body region divided radially into predetermined numbers having the barycenter of the body region as the

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center, is contracted until the circle circumscribes the muscle region which is extracted by performing threshold processing to the body region” (Rosania: Page 4, Paragraph 0053-0056, and See Figure 1E and F, Rosania describes a segmentation and distribution determination technique in which circumscribing circles, radial divisions, and thresholds are used to determine the organization of a cellular object by determining the distribution of the cellular components).

It would have been obvious to one of ordinary skill in the art to incorporate the distribution and organization technique of Rosania into the tissue fat content quantification of Sabol as modified by Kim, Wiemker, and Kvist because all are directed to segmenting and determining the content and content distribution of medical images. Furthermore, Rosania’s method is especially suited for determining organization of an image with respect to various components with in the image such as Rosania's cell nucleolus and plasma membrane which could be utilized for muscle and fat regions etc, and therefore yield the predictable result of determining more detailed information about the temporal-spatial dynamics of Sabol’s anatomical images.

With respect to claim 22, Sabol as modified by Kim, Wiemker, and Kvist teaches “further comprising means for extracting a navel region of the subject from the tomographic image of the subject” (Kim: See Figures 2-5, naval region corresponds to Kim’s image centers), “wherein the separation means extracts a region where muscle and bone region are removed” (Kim: Col. 3, lines 10-21 removed muscle and bone region correspond to Kim's narrowed Hounsfield value range), “as the subcutaneous

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adipose region from a portion of the body region included in a circular area of interest”

(Kim: Col. 3, lines 15-38, and See Figure 3),

It is however noted that both Sabol, Kim, Wiemker, and Kvist fails to teach “in which a radius of the circular area is half of a distance between a first attention point set at a peripheral edge of the non-adipose region and a second attention point set at middle point of each partial region of the muscle and bone region included in the regions where the navel region is removed from the extracted body region” as claimed.

On the other hand Sabol as modified by Kim, Wiemker, Kvist and Rosania teach “in which a radius of the circular area is half of a distance between a first attention point set at a peripheral edge of the non-adipose region and a second attention point set at middle point of each partial region of the muscle and bone region included in the regions where the navel region is removed from the extracted body region” (See Figure 1F, Rosania's right-side middle box, Rosania's inner circular area is about half the radius of the larger circle, therefor for the region between circles, the distance is half the radius of the large circle).

It would have been obvious to one of ordinary skill in the art to incorporate the distribution and organization technique of Rosania into the tissue fat content quantification of Sabol as modified by Kim, Wiemker, and Kvist because all are directed to segmenting and determining the content and content distribution of medical images. Furthermore, Rosania's method is especially suited for determining organization of an image with respect to various components with in the image such as Rosania's cell nucleolus and plasma membrane which could be substituted for muscle and fat regions

etc, and therefore yield the predictable result of determining more detailed information about the temporal-spatial dynamics of Sabol's anatomical images.

**18. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sabol et al., U.S. Patent Publication No. 2004/ 0101086 A1, filed on 10/27/2002, Kim et al., U.S. Patent No. 6278761, published on 08/21/2001, Wiemker et al., PCT WO 02/103065, published 12/27/2002, [herein Wiemker], Kvist et al., "Total and visceral adipose-tissue volumes derived from measurements with computed tomography in adult men and women: predictive equations.", published on 1988, [herein Kvist], and Wollenweber, US Patent No. 7155047 B2, filed on 12/20/2002, as applied to claim 7 above and further in view of Griffin et al. U.S. Patent Application Publication No. 2004/0207625A1, filed on 04/18/2003, [herein Griffin].**

With respect to claim 23, Sabol as modified by Kim, Wiemker, Kvist, and Wollenweber teaches "further comprising means for extracting a navel region of the subject from the tomographic image of the subject" (Kim: See Figures 2-5, naval region corresponds to Kim's image centers), "wherein the determination means determines that the tomographic image is suitable for body adipose measurement" (Wollenweber: Col. 7, lines 5-34, & 54-62, and Figure 2, item 68, determination of suitable image corresponds to Wollenweber's thresholding to determine images with quality problems), "when the navel region is included in the extracted non-adipose region" (Kim: See figures 3-6).

It is however noted that Sabol, Kim, Wiemker, Kvist, and Wollenweber fail to teach “when the air region is within a predetermined ratio”, as claimed.

On the other hand Griffin teaches “when the air region is within a predetermined ratio” (Page 17, Paragraph 0236).

It would have been obvious to one of ordinary skill in the art to incorporate the ratio of open air target and null target data of Griffin into the modified quantifying fat tissue content of Sabol as modified by Kim, Wiemker, Kvist, and Wollenweber, because all are directed to medical imaging and particularly Sabol, Kim, Wiemker, Kvist, and Griffin are all directed to establishing tissue content, moreover, both Wollenweber and Griffin are specifically directed to establishing quality metrics regarding the obtained image data. Furthermore, incorporating Griffin into Sabol as modified by Kim, Wiemker, Kvist, and Wollenweber would have allowed users of Sabol’s system to not only determine the quality of an obtained image but also further improve the system to account for imaging system artifacts as suggested by Griffin (Page 17, Paragraph 0235 and 0237), and thus yield the predictable result of obtaining reduced noise image data.

**19. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wiemker et al., PCT WO 02/103065, published 12/27/2002, [herein Wiemker], and further in view of Kvist et al., “Total and visceral adipose-tissue volumes derived from measurements with computed tomography in adult men and women: predictive equations.”, published on 1988, [herein Kvist], and Kim et al., U.S. Patent No. 6278761, published on 08/21/2001, [herein Kim].**

With respect to claim 26, Wiemker teaches “A medical image diagnosing support apparatus” (Page 7, lines 1-16),

“comprising: a first extraction means which extracts a body region of a subject from a tomographic image of the subject acquired by a medical tomographic apparatus” (See Figure 2, item 6, extract corresponds to visualize), “and removes an epidermal tissue layer region from the body region” (See Figure 2, item 7, the skin has been removed as illustrated from image 6 to image 7, by making the skin transparent);

“a second extraction means which extracts a non-adipose region from the body region from which an epidermal tissue layer region has been removed” (See Figure 2, items 7 & 8, and Page. 8, lines 15-28, extracting non-adipose region corresponds to Wiemker’s visualizing muscle);

“a display control means which controls display of the tomographic image on an image display device” (See Figure 2, and Page. 8, lines 15-28)

It is however noted that Wiemker fails to disclose “a third extraction means which extracts, based on both of the non-adipose region and the body region from which the epidermal tissue layer region has been removed, a total body adipose region from the body region from which the epidermal tissue layer region has been removed”;

“a separation means which separates the total body adipose region into a visceral adipose region and a subcutaneous adipose region based on positional information of the non-adipose region”; and

[displaying] “with clear indication of the visceral adipose region and the subcutaneous adipose region”, as claimed.

On the other hand Wiemker as modified by Kvist teaches “a third extraction means which extracts, based on both of the non-adipose region and the body region from which the epidermal tissue layer region has been removed, a total body adipose region from the body region from which the epidermal tissue layer region has been removed” (Kvist: Page 1352, Col. 2, final 2 paragraphs and Page 1353, Col. 1, and Col. 2, lines 8-12, total body adipose corresponds to Kvist’s total AT, which is established by first determining the muscle wall, and in view of using the narrowed ranges of the Hounsfield values as described by Wiemker, which makes skin transparent);

“a separation means which separates the total body adipose region into a visceral adipose region and a subcutaneous adipose region based on positional information of the non-adipose region” (Kvist: Page 1352, Col. 2, final 2 paragraphs and Page 1353, Col. 1, and Col. 2, lines 8-12).

It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to incorporate the teachings of Kim into the apparatus for segmenting medical images of Wiemker because both Kim and Wiemker are directed to medical imaging specifically for viewing body tissue, more particularly both are directed segmenting and distinguishing between the types of imaged body tissue and both are in the same field of endeavor. Furthermore, Wiemker contains a base process utilizing Hounsfield values for specific region visualization, which the claimed invention can be seen as an improvement in that adipose regions may be identified, measured, and visualized. Kvist contains a known technique of measuring and identifying adipose regions similarly utilizing Hounsfield values, and is therefore applicable to the case

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process. Moreover, Kvist's known technique of adipose identification and determination would have been recognized by one skill in the art as applicable to the "base" process of Wiemker and the results would have been predictable and resulted in determining adipose regions with respect to the abdominal muscle and excluding skin which results in an improved process.

It is still however noted that the combination still fails to explicitly disclose [displaying] "with clear indication of the visceral adipose region and the subcutaneous adipose region", as claimed.

On the other hand Wiemker as modified by Kvist and Kim teaches [displaying] "with clear indication of the visceral adipose region and the subcutaneous adipose region" (Col. 3, lines 18-38, clear indication corresponds to Kim's high contrast image).

It would have been obvious to one of ordinary skill in the art to incorporate the clear indication displaying of Kim into the modified visualization of body tissue of Wiemker as modified by Kvist because all are direct to the same field of endeavor which is medical imaging, particularly segmenting body regions. Wiemker as modified by Kvist contains a base process the identifies non-adipose and adipose regions and further separates the adipose regions, which the claimed invention can be seen as an improvement in that it displays the regions so that the differing adipose regions may be distinguished. Kim contains a known technique of distinguishably displaying the various adipose regions, which also utilized Hounsfield values that is applicable to the "base" process. Kim's known technique of displaying would have been recognized by one skilled in the art as applicable to the based process of Wiemker as modified by Kvist



and the results would have been predictable and resulted in displaying the different types of adipose so that measurement and diagnosis may be made easier.

### ***Response to Arguments***

**20. Applicant's arguments filed 11/29/2010, under REMARKS have been fully considered but they are not persuasive.**

In response to Applicant's arguments on pages 11-12, that Wiemker fails to teach removing an epidermal tissue layer from the body region, and extracting abdominal wall muscle from the region which the tissue has been removed, Examiner disagrees and notes the rejection above. Wiemker illustrates in figure 2 that the abdominal muscle wall is visualized in body region in which the skin has been removed by limiting the visualization to a range which the muscle is extracted. That is, the muscle beneath the skin could be visualized without the skin being removed; hence the skin is visually removed.

### ***Conclusion***

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JULIAN D. BROOKS whose telephone number is (571)270-3951. The examiner can normally be reached on Monday to Thursday EST 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Vikram Bali can be reached on 571-272-7415. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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/Julian D Brooks/  
Examiner, Art Unit 2624

02/26/2011

/VIKKRAM BALI/  
Supervisory Patent Examiner, Art Unit 2624